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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/813,482 | 03/30/2004 | Paula Olhoft | 600.479US2 | 4796 |
| 21186 | 7590 | 03/13/2007 | EXAMINER | |
| SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402 | | | HELMER, GEORGIA L | |
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| | | | 1638 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/813,482 | OLHOFT ET AL. |
| | Examiner | Art Unit |
| | Georgia Helmer | 1638 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 December 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 57-75 is/are pending in the application.
- 4a) Of the above claim(s) 69 and 70 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 57-68 and 71-75 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/30/04</u> . | 6) <input type="checkbox"/> Other: _____. |

Office Action

Restriction/Election

1. The Office acknowledges the timely receipt of Applicants restriction election, dated 4 December 2006, with traverse.

Applicant elects Group I (claims 57-61 and 63-75) directed to a method for the stable transformation of monocot tissue or cells. Applicant further elects a specie from an agent (species a-f) and a plant (species i-iv), electing the specie a, a sulphydryl-containing agent, and specie i, the specie maize.

Applicant traverses primarily that the inventions are closely related, that restriction requirements are optional in all cases, and that the species are related. The relationship for the agent is species a-f is that they enhance plant transformation. The relationship for the plants in species i-iv is that they are monocots. See (Response, p. 5, 1st ¶).

Applicant's traversal is persuasive in part. Groups I and II are hereby rejoined. Plants species i. through iv. are hereby rejoined.

Applicant's traversal for the Agent species has been considered and is found to be unpersuasive. Applicant traverses that the species have a relationship, that they enhance plant transformation. (Response, p. 6, final ¶). The Agents are (a) A sulphydryl-containing agent, (b) Methionine, (c) An iron chelator, (d) A copper chelator, (e) An inhibitor of plant polyphenol oxidase and (f) An inhibitor of plant peroxidase. These are chemically distinct species in the case of (a) and (b), and are described according to function for (c) through (f), without reference to structure. These clearly

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have different functions and different structures, and searching invention (a) –(f) together would impose an undue search burden. The prior art search for the different agents used in the methods are not coextensive. A search of each of these inventions would require different key word searches of each compound, and each step, of the methods, using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination.

Status of the Claims

2. Claims 57-75 are pending. Claims 69 and 70 are withdrawn as being drawn to a nonelected invention(s). Claims 57-68 and 71-75 are examined in the instant action.

Information Disclosure Statement

3. The Information Disclosure Statement dated 30 March 2004 is acknowledged. A signed copy of these documents is included in this Office Action.

Claim Rejections - 35 USC § 102

4. Claims 58-68 and 71-74 are rejected under USC 102 (b) as being anticipated by Perl, et. al., Biotechnology, Vol. 14, No. 5, 1996, pages 624-628. (Applicant's IDS).

Applicant's claims are drawn to a method of transformation of grape plant tissue or cells, by mixing the plant tissue or cells with Agrobacterium, a sulphydryl-containing agent in an amount effective to enhance the stable transformation of the plant tissue or cells. The sulphydryl-containing agents include cysteine, dithiothreitol, glutathione and sodium thiosulfate. Applicant's invention is in the field of plant transformation

Perl teaches a method for the stable transformation of grape (*Vitis vinifera L.*) comprising contacting embryogenic callus tissue and Agrobacterium containing recombinant DNA (p. 627, 1st column, 3rd full ¶) with the sulphydryl-containing agent cysteine (p. 625, Table 1) or dithiothreitol (p. 625, Table 1), where these agents are present in a solid medium (p. 625, Table 1), wherein the efficiency of stable formation is enhanced by at least 5-fold, or at least 0.5% or 10% greater than in the absence of the agent (p.626 last full ¶ & p. 627, 1st full ¶), where the transformed tissue is identified by hygromycin selection (p. 626, Table 2), wherein stable transgenic grape plants are regenerated (Abstract, lines 8-9) and wherein a recombinant DNA contains selectable detectable markers (p. 626 and 627, column 1).

Grape is a dicot plant. The Agrobacterium used contained nopaline synthase promoter-hygromycin coding sequence DNA (p. 627 Figure 5 legend) that has transferred to the transgenic grape plant material. This DNA functions as a selectable marker, as well as a detectable marker, since hygromycin can be applied to grape tissue, and only transgenic plant tissue will survive. The sulfhydryl-containing agents cysteine or dithiothreitol were present in solid medium with the Agrobacterium/grape plant material (p. 625, Table 1). The transgenic grape tissue was selected using hygromycin as shown by the number of tissue clusters which grew and developed on the Hyg selection medium, as well as by molecular characterization of the tissue using DNA analysis of genomic DNA from grape transgenic tissue. The concentration of dithiothreitol used by Perl et. al. is from 0.5 mg/ml – 5 mg/ml, which is included in the range of 1 mg/ml (=1 g/L).

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Perl et. al. indicate that "in this study, when embryogenic [grape] calli were cocultivated with different ...Agrobacterium strains, cell death took place, eliminating the possibility of using Agrobacterium as a transformation vehicle. Only in a combination of antioxidants [including cysteine or dithiothreitol] used during transformation enabled the recovery of transgenic plants." See p. 626, last full ¶. This is interpreted to mean that Perl et. al. teaches the conditions for obtaining some transformants of grape using Agrobacterium as compared to getting no transformants with Agrobacterium. Mathematically, dividing a number by zero is a very large number (infinity?). Therefore, since Perl et. al.'s data do not directly lend themselves to percentage or fold-ness terms, the data of Perl et. al. is interpreted by the Examiner to read on 0.5%, 10% or 5-fold enhancement of transformation (claims 63 and 64).

Accordingly Perl et al anticipate the claimed invention.

5. Claims 57-60, 62, 64-67, 71-73 and 75 are rejected under USC 102 (b) as being anticipated by Enriquez-Obergon et al, Genetic Transformation of Sugarcane by Agrobacterium tumefaciens using antioxidant compounds; Biotechnologia Aplicada, vol 14, pages 169-174, 1997.

Applicant's claims are drawn to a method of transformation of sugarcane plant tissue or cells, by mixing the plant tissue or cells with Agrobacterium, a sulfhydryl-containing agent comprising cysteine in an amount effective to enhance the stable transformation of the plant tissue or cells. Sugarcane is a monocot plant. Applicant's invention is in the field of plant transformation

Enriquez-Obergon et al teach a method for the stable transformation of the monocot sugarcane comprising contacting meristematic stem tissue and Agrobacterium containing recombinant DNA (p. 170, Figure 1) with the sulfhydryl-containing agent cysteine (p. 170, Table 1), where the cysteine was present in a solid medium (p. 172, column 1, 1st full sentence), wherein the efficiency of stable transformation is enhanced by at least 0.5% or 10% greater than in the absence of the agent, where the transformed tissue is identified by selection (Abstract, lines 5-7), and wherein a recombinant DNA contains selectable detectable markers (p. 170 Figure 1). Enriquez-Obergon et al teach the regeneration of stable Agrobacterium transformed transgenic sugarcane plants. See p. 174, 2nd column, final ¶.

Sugarcane is a monocot plant. The Agrobacterium used contained maize ubiquitin promoter-BarR coding sequence DNA and a CaMvirus 35S promoter operably linked to a uidA (GUS) coding sequence. This DNA functions as a selectable marker for Bar-resistance, as well as a detectable marker, since the uidA (GUS) coding sequence expression allows visualization by causing the development of blue color under the proper conditions. The sulfhydryl-containing agent cysteine was present in solid medium with the Agrobacterium/grape plant material (p. 172, column 1, 1st full sentence).

Enriquez-Obergon et al indicate that “[t]he use of an antioxidant mix [including cysteine] caused an 80% cell death decrease in respect to the controls...”. (Abstract, lines 5-7). “In this study we demonstrated that...cysteine ...can decrease the hypersensitivity reaction on the cut zone in the sugarcane meristematic explants. The decrease of cell death rates after cutting improved the competence of plant tissue to the Agrobacterium-mediated gene transformation. In the opposite cases, a fast hypersensitive response made the transformation impossible.” (p. 173, ¶ bridging p.174). The Examiner interprets this information to mean that the transformation rate was enhanced by at least 0.5% or 10% compared to the efficiency of transformation in the absence of the cysteine.

Accordingly, Enriquez-Obergon et al anticipate the claimed invention.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58-68 and 71-~~74~~ are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,759,573. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claims of patent 6,759,573 renders the genus claims of the instant application obvious.

Remarks

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10-6 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Georgia Helmer PhD
Patent Examiner
Transgenic Plants – art unit 1638
5 March 2007

A handwritten signature in black ink, appearing to read "Georgia Helmer".